

Remarks

Upon entry of the instant amendment, claims 24-35, and 56-75 are pending. Claims 1, 13, 17-19, and 36-55 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter encompassed by all canceled claims in one or more divisional or continuation applications. Applicants thank the Examiner for indicating the allowability of claims 24-26, 28-32, and 34-35. No new matter has been added by way of the instant amendment. Furthermore, the title was amended to read more precisely on the claimed subject matter.

Examiner Interview Summary

Applicants would like to thank Examiners Sullivan and Ketter for the phone interview accorded on February 27, 2003 in the present application. During the interview, rejections of the pending claims under 35 U.S.C. § 112, first paragraph for alleged lack of written description were discussed. More specifically, regarding the rejection of claims 56-75, which claim fragments “consisting of at least 35-50 contiguous amino acid residues of amino acid residues 1-121 of SEQ ID NO: 85”, Applicants pointed out that said claims contained “consisting of” language. Examiner Sullivan consulted a practice specialist at the U.S.P.T.O and later informed Applicants that such language would not sustain a rejection under lack of written description, which is addressed below.

Withdrawn Rejections

Applicants would like to thank the Examiner for finding Applicants’ arguments persuasive and withdrawing the provisional rejection of claims 30, 31, or 32 under the doctrine of double patenting, the rejection of claims 28, 34, 39, 44, 49, 54, 59, 64, and 74 under 35 U.S.C. § 112, first paragraph, and the rejection of claims 24-28, 30, 33, 38, 41, 43, 48, 53, 58, 63, 68, and 73 under 35 U.S.C. § 112, second paragraph.

Rejection of claims 27, 33, and 36-75 under 35 U.S.C. § 112, first paragraph

Claims 27, 33, and 36-75 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description for reasons of record in Paper No. 13. See, Paper No. 18, page 3, second paragraph.

A. The Examiner has maintained the rejection of claims 36-55 under 35 U.S.C. § 112, first paragraph. In particular, the Examiner asserts that the disclosure does not describe the genus of any and all polypeptides consisting that are 90% or 95% identical to SEQ ID NO: 85. *See*, Paper No. 18, page 3, lines 9-14.

Applicants respectfully disagree. However, in the interest of facilitating prosecution, claims 36-55 have been canceled and therefore, the rejection of claims 36-55 under 35 U.S.C. § 112, first paragraph is now moot. Applicants respectfully request that the rejection of claims 36-55 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

B. In regard to claims 27, 33, 38, 43, 53, 58, 63, 68, and 73, the Examiner asserts that Applicants did not address the grounds for rejection in the reply to Paper No. 13. Applicants respectfully disagree but have nonetheless more particularly addressed the rejection below. In particular, the Examiner has asserted that “the disclosure does not adequately describe the genus of any and all polypeptides heterologous to SEQ ID NO: 85.” *See*, Paper No. 18, page 3, third paragraph. Applicants respectfully disagree and traverse.

Preliminarily, Applicants note that claims 36-55 have been canceled without prejudice or disclaimer, hereby rendering the rejection moot. Applicants respectfully request that the rejection of claims 36-55 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991), M.P.E.P. § 2163.02.

Applicants respectfully point out that, based on a fair reading of the specification, the skilled artisan would reasonably conclude that Applicants were in possession of the claimed subject matter. For example, the specification discloses at page 279, line 29 to page 281, line 11 many heterologous sequences that may be fused to the polypeptides of the invention (*e.g.*, His-tag, HA-tag, protein A, IgG domains, maltose binding protein, IgG-1, IgG-3, Fc domains of IgG, and albumin). Further, at page 124, line 4 to page 125, line 30, the specification discloses additional molecules to which the polypeptides of the invention can be fused (*e.g.*, CD4-polypeptide; and constant domains of IgA, IgE, IgG, IgM).

Therefore, given the extensive disclosure in the specification, Applicants assert that the specification adequately describes the genus of the subject matter of claims 27 and 33. Thus,

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27, 33, 58, 63, 68, and 73 under 35 U.S.C. § 112, first paragraph.

C. The Examiner has maintained the rejection of claims 56-75 under 35 U.S.C. § 112, first paragraph. In particular, the Examiner asserts that the disclosure does not describe the genus of any and all polypeptides consisting of at least 30-50 contiguous amino acid residues of amino acid residues 1-121 of SEQ ID NO: 85. *See*, Paper No. 18, page 3, lines 9-14.

Applicants respectfully disagree and traverse.

Preliminarily, Applicants respectfully point out that independent claims 56, 61, 66, and 71 recite “consisting of” language.

As stated above, the test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991), M.P.E.P. § 2163.02.

Further, Applicants respectfully point out that the Federal Circuit court has recently held that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *University of California v. Eli Lilly*, 119 F.3d 1559, 1569 (Fed. Cir. 1997) (hereinafter “*Eli Lilly*”). Thus, the Federal Circuit indicated that the written description requirement for generic claims to genetic material, such as cDNA, may be satisfied by providing the sequences of a representative number of nucleic acids which fall within the scope of the genus or by providing a recitation of structural features common to a substantial portion of the members of the genus. Therefore, it logically follows that claims to polypeptides encoded by cDNAs may also be satisfied by providing sequences of a representative number of polypeptides which fall within the scope of the genus or by providing a recitation of structural features common to a substantial portion of the members of the genus.

Applicants assert that, while not required, both tests set forth in *Eli Lilly* have been satisfied in the instant case. For instance, to the satisfaction of the first test set forth in *Eli Lilly*, and contrary to statements made by the Examiner, Applicants’ description of the complete amino acid sequence of SEQ ID NO: 85 provides one skilled in the art with the sequence of a representative number of polypeptide fragments consisting of 30 to 50 contiguous amino acid

residues from SEQ ID NO: 85. Because claims 56, 61, 66, and 71 recite “consisting of” language, the skilled artisan would be readily able to envision such fragments. Furthermore, the second test set forth in *Eli Lilly* is also fulfilled because Applicants’ description of the sequence reference polypeptide SEQ ID NO: 85 and fragments thereof provides one skilled in the art with the necessary recitation of structural features common to members of the genus, which features “constitute a substantial portion of the genus.” Applicants point out that the recitation of the structural features of the reference protein is a recitation of the structural features common to the members of the claimed genus because the proteins included within the claimed genus will have 30 and 50 contiguous amino acids of their amino acid sequence (primary structure) in common to the reference polypeptide of SEQ ID NO: 85. Once one of ordinary skill in the art is enlightened by the specification and provided with, for example, the reference polypeptide sequence of SEQ ID NO: 85, the skilled artisan could readily envision and derive any number of polypeptide fragments that would consist of 30 or 50 amino acids of the reference polypeptide sequence. Therefore, in accord with *Eli Lilly*, the description of the species is a recitation of structural features common to a substantial portion of the members of the genus and the specification clearly conveys that Applicants were in possession of the claimed invention on the priority date of the instant application. Further, as discussed in the Examiner’s Interview above, per the Patent Office’s policy regarding written description, as currently written, claims 56-75 would not sustain a rejection under 35 U.S.C. § 112, first paragraph.

In view of the above comments, Applicants assert that the claimed polypeptides are adequately described and respectfully request that the rejection of claims 56-75 under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

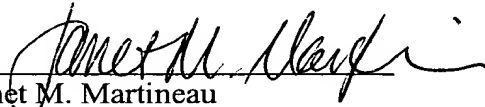
Conclusion

Applicants respectfully request that the above-made amendment and remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

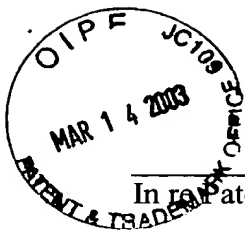
If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: March 14, 2003

Respectfully submitted,

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VIA HAND DELIVERY MARCH __, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Docket No.: PZ003P4

Ruben, et al.

Application No.: 09/852,659

Group Art Unit: 1636

Filed: May 11, 2001

Examiner: D. Sullivan

For: **Secreted Protein HPMBQ91** (as amended
herein)

VERSION WITH MARKNGS TO SHOW CHANGES MADE

In the Title

The title was amended as follows:

~~28 Human Secreted Proteins~~ **Secreted Protein HPMBQ91**